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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,078	BOUWSTRA ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) *11,12,15 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13,16 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13 and 15-20 are pending.

Applicants' request for rejoinder is acknowledged. However, the current status of the rejoinder practice allows to rejoin the withdrawn process claims upon allowance of the elected product claims. It is noted that Applicants have elected the process claims and the product claims have withdrawn. MPEP 821.04.

Claims 11, 12, 15 and 17 stand withdrawn from further consideration by the examiner 37CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-10, 13, 16 and 18-20, drawn to a method for the preparation of a vaccine composition are under consideration in the instant application.

2. In light of Applicants' amendments to the claims filed on 11/24/08, the objection and the rejection under the second paragraph of 35. U.S.C.112 (sections 6-7) have been withdrawn.

3. Claim 4 is objected to because of the following informalities: Claim 4 recites a number of molecular weight ranges in Markush format but the conjunction "and" is missing.

4. The following rejections remain.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application

filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-10, 13, 16 and 18-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/34801 (IDS reference, of record) as is evidenced by U.S. Pat. No. 6,685,940B2, of record, for the reasons set forth in the office action mailed 7/17/08.

The '801 publication teaches a method of producing a vaccine formulation comprising an antigen and a recombinant gelatin (p. 86, claims 39, 1, 18-19) and the vaccine formulation is lyophilized (p. 66-67). The '801 publication further teaches that the molecular weight of gelatin includes 10 to 30kDa and about 8kDa or 9KDa (p. 8, lines 10-15).

Given that the referenced vaccine composition comprising a gelatin and antigen is dry and powder (claims 18-19), the referenced lyophilization results in dryness of the composition, the claimed "water content remains below 2wt.%" has met and the prevention of recombinant gelatin from crystallization is inherently achieved.

Moreover, the '801 publication teaches that the recombinant gelatin is homogenous (p. 40), claim 2 reciting "homodisperse" ,which means at least 90% of gelatin has molecular weight lies within +/- 10% around the selected molecular weight (specification 10), and claim 5 and 20 reciting "optimally aligned by GAP" are included in this rejection (p.17-18, overlapping paragraph).

Claim 8 reciting "prevent crystallization of the recombinant gelatin for at least 7 years" is included in this rejection because having the dried vaccine formulation upon lyophilization meets the claimed limitation of "water content is maintained below 2 weight percent" and prevention of crystallization of the recombinant gelatin for at least 7 years is inherently achieved.

Furthermore, claims 9-10 reciting "providing the composition in a sufficiently moisture-tight container" and "providing the composition in a sufficiently air-tight container", respectively, are included in this rejection because the '801 publication teaches a preparation method of vaccine and manufacturing in a kit (p. 67, claims 41-45). The specification of the instant application defines air-tight or moisture tight container as vials (p. 9) and the evidentiary reference '940 patent discloses that a lyophilized protein is

packaged in a vial in a kit. Given that a kit inherently comprises a container and this container prevents any leakage, therefore, the container is a sufficiently air or moisture tight container.
Therefore, the reference teachings anticipate the claimed invention.

Applicants' arguments filed on 11/24/08 have been fully considered but they were not persuasive.

Applicants have argued that the teachings of the '801 publication are not aware of problems associated with the use of recombinant gelatin as a stabilizer. The heterogeneous nature of animal-derived gelatin is associated with the crystallization. Applicants have further argued that the term "dry" used in the '801 publication is a relative term and the term "dry" retains some unspecified proportion of water and the claimed limitation is not met by the reference teachings. Moreover, Applicants have argued that the lyophilization used in the '801 publication does not prevent the crystallization of gelatin for at least 7 years as required by claim 8.

However, applicants' assertion regarding that the teachings of the '801 publication are not aware of problems associated with the use of recombinant gelatin as a stabilizer is irrelevant. The instant claimed method relates to a method for preparation of a vaccine comprising recombinant or synthetic gelatin by reducing water content below 2% of the vaccine and maintaining the water content of 2%.

As discussed previously, the '801 publication teaches a vaccine composition comprising a recombinant gelatin and the formulation is lyophilized and dry (claims 1-7, 18 and 19, p. 66-67). Unlike applicants' assertion that some lyophilization process result in the water content higher than 2% (p. 10, response filed on 11/24/08), the referenced process results in "dry" formulation as recited in the referenced claim 18.

As is defined by the Webster's II New Riverside University Dictionary on p. 408, the term "dry" is free from moisture or liquid, having all the water or liquid drained away, or evaporated. Given that "all" liquid is removed by the process of reducing water (e.g. lyophilization), the referenced process meets the claimed limitation of "reducing water content of the vaccine composition to be below 2%".

Applicants' assertion of having the container of the kit does not anticipate the claimed limitation because the container could leak or might not be sufficiently air tight. Given that the specification of the instant

application on p.9 discloses "vials" as means for maintaining the water content below 2%, the referenced vial will inherently serve the intended use.

Moreover, Applicants' assertion that the referenced lyophilized vaccine is not stable for 24 months of storage and the citation of p.60 as a basis for the assertion is misleading.

The passage reads:

> Lyophilized vaccines slowly deteriorate until, at around 12 to 24 months of storage, the vaccine formulation lacks sufficient titer to confer immunization.

However, the above passage is related with problems associated with general lyophilzation in vaccine art in the absence of any type of stabilizer and the reference highlights importance of stabilizer and synergistic effect upon addition of a stabilizer (p. 61). The '801 publication states:

> "Therefore, the recombinant gelatins used, in the preparation and manufacture of vaccines and/or as stabilizers and components of vaccines, can be produced according to the present methods to have controlled and particular characteristics. Use of the present gelatins thus permits vaccine makers an opportunity to fine-tune and minimize variability in their production processes, as well as to use recombinant gelatin in a more effective and more cost-efficient manner." (p.65)

As discussed above, the referenced vaccine formulation comprising recombinant is produced by the lyophilzation which results in dry formulation and packaged in a vial, the limitations of the claimed method comprising reducing the water content below 2% and maintaining the water content below 2% have met. Therefore, the reference teachings anticipate the claimed invention.

7. Claims 1-10, 13, 16 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pub. 20030064074 (IDS reference, of record) as is evidenced by U.S. Pat. No. 6,685,940B2, of record, for the reasons set forth in the office action mailed on 7/17/08.

The '074 publication teaches a method of producing a vaccine formulation comprising an antigen and a recombinant gelatin (p. 23-24, [0221-0232], claims 47, 1, 26-28) and the vaccine formulation is lyophilized (p. [0231]). The '074 publication further teaches that the molecular weight of gelatin includes 10 to 30kDa and about 8kDa (p. 3, [0028]).

Given that the referenced vaccine composition comprising a gelatin and antigen is dry and powder (claims 26-28), the referenced lyophilization results in dryness of the composition, the claimed "water content remains below 2wt.%" has met and the prevention of recombinant gelatin from crystallization is inherently achieved.

Moreover, the '074 publication teaches that the recombinant gelatin is homogenous (p. 16, [0162-165]), claim 2 reciting "homodisperse" ,which means at least 90% of gelatin has molecular weight lies within +/- 10% around the selected molecular weight (specification 10), and claim 5 and 20 reciting "optimally aligned by GAP" are included in this rejection ([0081]).

Claim 8 reciting "prevent crystallization of the recombinant gelatin for at least 7 years" is included in this rejection because having the dried vaccine formulation upon lyophilization meets the claimed limitation of "water content is maintained below 2 weight percent" and prevention of crystallization of the recombinant gelatin for at least 7 years is inherently achieved.

Furthermore, claims 9-10 reciting "providing the composition in a sufficiently moisture-tight container" and "providing the composition in a sufficiently air-tight container", respectively, are included in this rejection because the '074 publication teaches a preparation method of vaccine and manufacturing in a kit (p. 4 [0032], claim 52). The specification of the instant application defines air-tight or moisture tight container as vials (p. 9) and the evidentiary reference '940 patent discloses that a lyophilized protein is packaged in a vial in a kit.

Given that a kit inherently comprises a container and this container prevents any leakage, therefore, the container is a sufficiently air or moisture tight container. Therefore, the reference teachings anticipate the claimed invention.

Applicants' arguments filed on 11/24/08 have been fully considered but they were not persuasive.

Applicants have argued that the teachings of the '0741 publication are not aware of problems associated with the use of recombinant gelatin as a stabilizer. The heterogeneous nature of animal-derived gelatin is associated with the crystallization. Applicants have further argued that the term "dry" used in the '074 publication is a relative term and the term "dry" retains some unspecified proportion of water and the

claimed limitation is not met by the reference teachings. Moreover, Applicants have argued that the lyophilization used in the '074 publication does not prevent the crystallization of gelatin for at least 7 years as required by claim 8.

As the '074 publication (U.S. Pub.) is equivalent to the '801 publication (WO) and in light of the discussion above in section 6, the reference teachings anticipate the claimed invention.

7. No claims are allowable.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
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February 6, 2009

/Michael Szperka/
Primary Examiner, Art Unit 1644